K090806

SUMMARY FOR FOI

Safi-gel Daily Disposable (methafilcon A) Soft (hydrophilic) Lens
Safi-gel Daily Disposable Toric (methafilcon A) Soft (hydrophilic) Lens
Safi-gel Daily Disposable Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens

1. Submitted by: Safilens, S.r.L.
Via Grazia Deledda, 5
34079 Staranzano (GO)
Italy

DEC 1 8 2009

Contact: John M. Szabocsik, Ph.D.

Official agent: Szabocsik and Associates
203 N. Wabash, Ste 1200
Chicago, IL 60601
(312) 553-0828

2. Date prepared: May 22, 2009

3. Device:

Common Name: **Safi-gel Daily Disposable (methafilcon A) Soft (hydrophilic) Lens**
Safi-gel Daily Disposable Toric (methafilcon A) Soft (hydrophilic) Lens
Safi-gel Daily Disposable Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens

Trade Name: **Safi-gel Daily Disposable (methafilcon A) Soft (hydrophilic) Lens**
Safi-gel Daily Disposable Toric (methafilcon A) Soft (hydrophilic) Lens
Safi-gel Daily Disposable Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens

4. Classification: Code LPL, Class II (Performance Standards)
21 CFR 886.5925
Soft (hydrophilic) contact lens

5. Substantial equivalence: This product is substantially equivalent to the 55 UV (methafilcon A) Soft (hydrophilic) Lens for Daily Wear, the 55 UV Multifocal (methafilcon A) Soft (hydrophilic) Lens for Daily Wear, and the 55 UV Toric (methafilcon A) Soft (hydrophilic) Lens for Daily Wear, cleared for market in K051095.

6. Device description: The lens material (methafilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate(HEMA) , methacrylic acid crosslinked with ethylene glycol dimethacrylate (45%). The hydrated lens contains 55% water by weight with hyaluropolymer and a UV absorbing compound (RUVA-93) incorporated into the lens polymer. The lens is tinted using Pigment Blue 15 (copper phthalocyanine). The lens acts as a refracting medium to focus light rays on the retina.

The **Safi-gel Daily Disposable (methafilcon A) Soft (hydrophilic) Lens** is available as a single vision lens, which incorporates a tangential back surface edge lift and bi-curve reduced optic front surface. The peripheral curve is tangential at the back optic zone.

The **Safi-gel Daily Disposable Toric (methafilcon A) Soft (hydrophilic) Lens** design incorporates a cylinder and base curve, and the peripheral curve is tangential with edge lift on the back surface. From the bi-curve reduced optic front surface, there exists a slab-off of the upper and lower half of the lens. This makes both sides thicker at the horizontal level on the front surface to keep the axis stable.

The **Safi-gel Daily Disposable Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens** is available as an aspherical multifocal lens.

The **Safi-gel Daily Disposable (methafilcon A) Soft (hydrophilic) Lens** is a hemispheric flexible shell of the following dimensions:

Diameter:	14.2 mm
Center Thickness:	0.08 mm (-3.00D) dry
Base Curves:	8.70 mm and 8.30 mm
Powers:	+4.00D to –6.00D (in 0.25D steps)
	+ 4.50D to +12.00D (in 0.50D steps)
	-6.50D to – 20.00D (in 0.50D steps)

The **Safi-gel Daily Disposable Toric (methafilcon A) Soft (hydrophilic) Lens** is a hemispheric flexible shell of the following dimensions:

Diameter:	14.5 mm
Center Thickness:	0.08 mm (-3.00D) dry
Base Curves:	8.70 mm
Powers:	+4.00D to –6.00D (in 0.25D steps)
	+ 4.50D to +12.00D (in 0.50D steps)
	– 6.50D to – 20.00D (in 0.50D steps)
Cylinder Power:	– 0.50DC to – 2.50D
Axis:	Full circle (in 10°steps)

The **Safi-gel Daily Disposable Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens** is a hemispherical flexible shell which covers the cornea and a portion of the adjacent sclera with the following dimensions:

Diameter: 14.0mm to 15.0mm
Center Thickness: 0.06mm to 0.40mm
Base Curve: 8.40mm to 9.30mm
Powers: +12.00 Diopters to -20.00 Diopters
Add Powers: Continuous add power to +3.25
Zone Sizes: 1.5, 1.9 mm

The physical/optical properties of the lens are:
Refractive Index: 1.410 (wet)
Light Transmittance: 90.3%
UV Transmittance 9.3%
Water Content: 55%
Oxygen Permeability: 18.9 x 10^{-11} at 35° C Coulometric Method

7. Intended use: The **Safi-gel Daily Disposable (methafilcon A) Soft (hydrophilic)Contact Lens** is indicated for daily disposable wear for correction of refractive ametropia (myopia, hyperopia) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The **Safi-gel Daily Disposable Toric (methafilcon A) Soft (hydrophilic) Contact Lens** is indicated for daily disposable wear for correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic or not-aphakic persons with non-diseased eyes.

The **Safi-gel Daily Disposable Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens** is indicated for daily disposable wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The **Safi-gel Daily Disposable Lenses** are to be prescribed for single-use disposable wear, and are to be discarded after each removal.

The product was shown to be substantially equivalent to the predicate device in physicochemical testing of water content, oxygen transmissibility, light transmission (visible and UV) and refractive index.

Toxicological testing of extracts of the **Safi-gel Daily Disposable (methafilcon A) Soft (hydrophilic) Contact Lens** demonstrated that the lenses were non-cytotoxic, showed no systemic toxicity, and showed no ocular irritation.

Microbiological testing was not required because the manufacture and packaging are the same as that for the predicate device, cleared in K051095.

Clinical testing was not required because the physical/chemical properties are the same as the predicate device, cleared in K051095.

Labeling was submitted as part of the application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Safilens, S.r.L.
c/o John M. Szabocsik, Ph.D.
Szabocsik and Associates
203 North Wabash Avenue
Suite 1200
Chicago, IL 60601

DEC 18 2009

Re: K090806
Trade Name: Safilens Safi-gel Daily Disposable (methafilcon A) Soft (hydrophilic) Contact Lens (sphere, toric and multifocal)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: November 30, 2009
Received: December 3, 2009

Dear Dr. Szabocsik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K090806

DEVICE NAME: **Safi-gel Daily Disposable (methafilcon A) Soft (hydrophilic) Lens**
Safi-gel Daily Disposable Toric (methafilcon A) Soft (hydrophilic) Lens
Safi-gel Daily Disposable Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens

INDICATIONS FOR USE

The **Safi-gel Daily Disposable (methafilcon A) Soft (Hydrophilic) Contact Lens** is indicated for daily disposable wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The **Safi-gel Daily Disposable Multifocal (methafilcon A) Soft (Hydrophilic) Contact Lens** is indicated for daily disposable wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic and not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The Safi-gel Daily Disposable Toric (methafilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily disposable wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not aphakic persons with non diseased eyes.

The **Safi-gel Daily Disposable Lenses** are to be prescribed for single-use disposable wear, and are to be discarded after each removal.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____(Per 21 CFR 801.109)
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K090806